IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORP.,	)	
Plaintiffs,	)	
v.	)	Civ. No. 98-80-SLR (consolidated with Civ. No. 98-314-SLR and Civ. No. 98-316-SLR)
MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC.,	)	
Defendants.	)	

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Karen Jacobs Louden, Esquire, and Leslie A. Polizoti, Esquire of Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware. Counsel for Defendants. Of Counsel: Raphael V. Lupo, Esquire, Donna M. Tanguay, Esquire, and James G. Rizzo, Esquire of McDermott Will & Emery LLP, Washington, DC, and Fay M. Morisseau, Esquire, Matthew F. Weil, Esquire, Michael R. O'Neill, Esquire, and David M. Stein, Esquire of McDermott Will & Emery LLP, Irvine, California.

OPINION

Dated: April 23, 2007
Wilmington, Delaware

ROBINSON, Chief J.

I. INTRODUCTION

A bench trial was held on defendants' defense and counterclaim that U.S. Patent Nos. 5,514,154 ("the '154 patent"), 6,066,167 ("the '167 patent"), 6,066,168 ("the '168 patent"), and 6,432,133 ("the '133 patent") (collectively, the "Lau patents") are unenforceable as a result of inequitable conduct. The issue was fully briefed post-trial. (D.I. 683, 686, 687) The court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201(a). Having considered the documentary evidence and testimony, the court makes the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(1).

II. FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Procedural History

1. The lawsuit originally was filed on February 18, 1998 by the predecessor in interest to Medtronic Vascular Inc. and Medtronic USA, Inc. (collectively, "Medtronic"), claiming infringement by Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation (collectively, "ACS") of certain of its patents ("the Boneau patents"). (D.I. 1) ACS countersued for infringement of the Lau patents.[1] Because judgment was entered in favor of ACS in connection with the Boneau patents (D.I. 546), the parties were "realigned" in order to proceed with the jury trial on the Lau patents. (D.I. 585)

2. A jury trial was held between February 7 and 18, 2005. (D.I. 631-39) At the conclusion of trial, the jury returned a verdict that the Lau patents were valid and

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[1]Although multiple Lau patents were asserted, only four were tried, that is, the '154 patent, the '167 patent, the '168 patent, and the '133 patent.

infringed by Medtronic. The jury found that each of Medtronic's accused stents infringe each asserted claim of the Lau patents. Specifically, the jury found Medtronic's MicroStent II, GFX, GFX2, GFX2.5, S540, S660, S670 and BeStent2 stents infringe claims 1 and 4 of the '154 patent, Medtronic's BeStent2 stent infringes claim 12 of the '154 patent, and that Medtronic's MicroStent II, GFX, GFX2, GFX2.5, S540, S660, S670, S7, Driver, MicroDriver, and Racer stents infringe claims 5 and 8 of the '167 patent. (D.I. 629) Additionally, the jury found that all of the aforementioned stents infringe claims 1, 3, and 11 of the '168 patent (with the exception of the MicroStent II, which infringes only claims 1 and 3), and infringe claims 1, 2, and 3 of the '133 patent. (Id.) The jury found that the BeStent2 stent also infringes claim 9 of the '133 patent. (Id.)

3. The court held a bench trial regarding Medtronic's inequitable conduct defense and counterclaim on June 7 and 8, 2005. (D.I. 670, 671)

B. The Patents In Suit and the Technology at Issue

4. The Lau patents generally relate to endovascular support devices, or stents, that are used in the treatment of cardiovascular disease. The '154 patent was originally filed on July 28, 1994 as U.S. Application No. 08/281,790 ("the '790 application"). The '790 application was a continuation-in-part application, and claimed priority to subject matter filed in an earlier, abandoned application filed on October 28, 1991.[2] Nine divisional applications were subsequently filed, including the applications which issued

[2]The '790 application was filed on July 28, 1994 as a continuation-in-part of U.S. Patent Application No. 08/164,986, filed December 9, 1993, which was a continuation of U.S. Patent Application No. 07/783,558, filed October 28, 1991. These two applications were subsequently abandoned.

as the '133, '167, and '168 patents. Each divisional application claimed priority through the chain of applications preceding it to the '790 application and, in turn, the October 28, 1991 filing date.[3] The Lau patents share a common specification.

5. Each of the Lau patents generally claim a longitudinally flexible stent comprising a plurality of independently expandable cylindrical elements aligned on a common axis. The '154 patent requires that adjacent cylindrical elements are interconnected with connecting elements. Independent claim 1 (and dependant claims 2-11) also requires that the stent has a smooth outer surface prior to expansion but forms a plurality of outwardly projecting edges upon expansion. Independent claims 12 and 23 (and dependant claims 13-22) generally require that the stent retains its length without shortening when the stent is expanded.

6. Independent claims 1 and 12 of the '133 patent require that the cylindrical elements have a length less than their diameter upon expansion. Claim 1 requires a length of less than 2.55 mm for the cylindrical element upon expansion, and claim 12 generally requires that the stent pattern has a plurality of undulating portions extending circumferentially about the longitudinal axis. Independent claim 15 also incorporates this plurality of undulating portions, and further requires that these undulating portions

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[3]U.S. Patent Application No. 08/783,097 ("the '097 application") was the second in a chain of divisional applications filed from the application which issued as the '154 patent. The '097 application issued on April 7, 1998 as U.S. Patent No. 5,735,893. Two divisional applications were filed from the '097 application. One was the divisional application that later issued as the '168 patent. The application that issued as the '133 patent was a later divisional filed in this chain. The other divisional filed from the '097 application was U.S. Patent Application No. 08/823,434 (later issuing as U.S. Patent No. 5,766,238); the application that issued as the '167 patent was a divisional filed from this application.

have open and closed ends, where at least one closed end is wider than an open end.

7. Claim 1 of the '167 patent requires that each cylindrically shaped element is independently expandable, and has an undulating pattern whereby the cylindrical elements are out of phase with adjacent cylindrical elements. Independent claim 5 additionally requires that the cylindrically shaped elements form a longitudinally flexible stent.

8. Claim 1 of the '168 patent requires that each cylindrical element is connected by at least one weld connection to an adjacent cylindrical element. Independent claim 12 additionally requires that the cylindrical elements are arranged out of phase, and that adjacent peaks of the cylindrical elements are connected by weld connections.

9. ACS's stents are balloon expandable devices that are formed from a metal tube. (D.I. 427 at 4) These stents are comprised of multiple circular elements that are connected together by connecting elements. (Id.) ACS sells its stents under the Multilink tradename.

C. Prior Art References

10. Defendants assert that the following constitutes material information withheld from the United States Patent and Trademark Office ("USPTO"): (1) U.S. Patent Application No. 07/398,180 ("the Boneau application"), which later issued as U.S. Patent No. 5,292,331 to Boneau ("Boneau '331"); and (2) "the Boneau prior art," a term which defendants use to describe, inter alia, "clinical data showing implantation of Boneau rings in a crown to crown configuration, and the connection of such rings at their crowns." (D.I. 683 at 5-6, 24, 27-28)

11. Michael Boneau ("Boneau") invented and bench tested the Boneau stent in

1988. (D.I. 683 at 5; D.I. 636 at 1213:12-1214:3) Also in 1988, Boneau began working with Dr. Simon Stertzer ("Stertzer"), a pioneer interventional cardiologist who was the first doctor to implant a stent in a human patient in the United States. (D.I. 670 at 35:7-36:22) Stertzer implanted multiple Boneau stents in a single artery (id. at 41:16-18),[4] in a manner which left only a small gap between the crowns of the stents (a "crown to crown" configuration) (id. at 41:19-43:7). According to Medtronic, "[b]y August 1988, based upon the disclosure of the Boneau application and the work done by [Boneau and Stertzer], the scope of the Boneau prior art included the use of multiple Boneau stents, each with a length less than its diameter, and the crown to crown alignment of stents." (D.I. 683 at 6) "The Boneau prior art" also encompasses Boneau's idea of connecting multiple Boneau stents with sutures. (Id. at 6-7) Boneau testified that he first conceived of connecting Boneau stents with sutures in March 1990, though he never tested this idea clinically, and did not file a patent application at that time. (D.I. 670 at 136:22-138:18)

12. The Boneau application was filed on August 24, 1989, and issued on March 8, 1994.[5] Prior to publication, Boneau provided at least one copy of the Boneau application to ACS in an attempt to obtain a license for his stent technology. (D.I. 686

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[4]It is unclear from the record exactly when Stertzer performed this task. Medtronic implies that Stertzer implanted multiple Boneau stents prior to August 1988 (D.I. 683 at 6), and this assertion is not disputed by ACS (D.I. 686).

[5]The Boneau application was not prior art under 35 U.S.C. §102(e) before this 1994 issue date. As the Federal Circuit has explained, "[m]ateriality is not limited to prior art but instead embraces **any** information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent." GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001) (emphasis in original) (citation omitted).

at 5) In January 1990 (and again in March 1990), ACS asked its outside patent counsel, Edward Lynch ("Lynch"), to review the Boneau application. (Id.; D.I. 671 at 532:7-12, 534:1-8) Boneau and Stertzer gave a formal presentation on the Boneau technology to ACS in late August or early September 1990. (D.I. 686 at 5)

12. The Boneau application generally discloses an expandable stent which has a zig-zag structure with a number of peaks (or turns) at each end. The specification[6] states that

> [t]he minimum length of the stent, or the distance between the upper turns 12 and lower turns 14, is determined in large measure by the size of the vessel into which the stent will be implanted. The stent 10 will preferably be of sufficient length as to maintain its axial orientation within the vessel without shifting under the hydraulics of blood flow (or other fluid flow in different types of vessels), while also being long enough to extend across at least a significant portion of the affected area. At the same time, the stent should be short enough as to not introduce unnecessarily large amounts of material as might cause undue thrombosis. Typical cardiovascular vessels into which the stent 10 might be implanted range from 1.5 millimeters to five millimeters in diameter, and corresponding stents may range from one millimeter to two centimeters in length. However, in most instances the stent will range in length between 3.5 millimeters and 6 millimeters. Preliminary testing of stents having a length between 3.5 millimeters and 4.5 millimeters has been performed with good success outside the United States, and testing on animals is also ongoing.

(Boneau '331, col. 5 ll. 14-36) The specification further states that

> [o]ne of the advantages of the stent 10 is that multiple stents may be used in the treatment of a single lesion. Thus, for example, in the event the affected area shown in FIGS. 3 and 4 was longer than the stent 10, additional stents 10 could be positioned elsewhere along the lesion to prevent restenosis . . . Due to the conformability of the stent 10, not only can varying lesion lengths be treated, but curved vessels and "S" shaped vessels may also be treated by the present invention. In instances where it is known in advance that multiple stents will be

[6]Because the specification of the Boneau application was not amended during prosecution and is identical to that of Boneau '331, the court will hereinafter reference the specification of Boneau '331 (AX-18) rather than the record in citing the Boneau application.

> the preferred method of treatment, a plurality of such stents may be positioned along a single balloon catheter for simultaneous delivery to the affected area.

(Boneau '331, col. 6 ll. 27-41)

13. Six figures are provided, which show a stent according to the invention, both in an expanded and unexpanded state, compressed into a balloon catheter for delivery, and expanded within a sectioned portion of a lesion after removal of the catheter. The use of multiple stents is not pictured.

D. Parties Charged with Inequitable Conduct

14. Defendants assert that the following individuals were aware of Boneau '331 but intentionally failed to disclose it to the USPTO: (1) Lilip Lau ("Lau"), coinventor of the Lau patents; (2) Elizabeth McDermott, Director of Research and Development for ACS, and to whom Lau reported during his stent development work; (3) Michael Orth ("Orth"), Business Manager of ACS's stent business unit; (4) Bruce Barclay, ACS's in-house patent counsel; (4) Lynch, who prosecuted the Lau patents until October 1992; and (5) Tony Nagy, ACS's outside patent counsel, who prosecuted the Lau patents from October 1992 onward. (D.I. 683 at 17-20)

E. Inequitable Conduct Standard

15. Applicants for patents and their legal representatives have a duty of candor, good faith, and honesty in their dealings with the USPTO. See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995); 37 C.F.R. § 1.56(a). This duty is predicated on the fact that "a patent is an exception to the general rule against monopolies and to the right of access to a free and open market." Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945). The duty of candor, good faith, and

honesty includes the duty to submit truthful information and the duty to disclose to the USPTO information known to patent applicants or their attorneys which is material to the examination of a patent application. See Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999). A breach of this duty constitutes inequitable conduct. Molins, 48 F.3d at 1178.

16. If it is established that a patent applicant engaged in inequitable conduct with respect to one claim, then the entire patent application is rendered unenforceable. See Kingsdown Med. Consultants v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988). Additionally, "[a] breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application." Fox Indus., Inc. v. Structural Pres. Sys., Inc., 922 F.2d 801, 803-04 (Fed. Cir. 1990).

17. A finding of inequitable conduct is "an equitable determination" and, therefore, "is committed to the discretion of the trial court." Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1261 (Fed. Cir. 2001).

18. In order to establish unenforceability based on inequitable conduct, a defendant must establish by clear and convincing evidence that: (1) the omitted or false information was material to the patentability of the invention; (2) the applicant had knowledge of the existence and materiality of the information; and (3) the applicant intended to deceive the USPTO. See Molins, 48 F.3d at 1178.

19. The Federal Circuit has recently stated that, prior to 1992, two standards for materiality were in effect: (1) the materiality standard set forth in the present version of USPTO Rule 56, 37 C.F.R. § 1.56(b) (2004); and (2) the previous version of that rule. See Digital Control Inc. v. Charles Machine Works, 437 F.3d 1309, 1314 (Fed. Cir.

2006). The Court in Digital Control held that the new 1992 iteration of Rule 56 was not intended to replace the broader old Rule 56, and "merely provides an additional test of materiality." Id. at 1316. Therefore, "if a misstatement or omission is material under the new Rule 56 standard, it is material. Similarly, if a misstatement or omission is material under the 'reasonable examiner' standard or under the older three tests, it is also material." Impax Labs., Inc. v. Aventis Pharm. Inc., 468 F.3d 1366, 1374 (Fed. Cir. 2006) (quoting Digital Control, 437 F.3d at 1316)).

20. Rule 56 currently states:

> Information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
> (i) Opposing an argument of unpatentability relied on by the Office, or
> (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b) (2006). Further,

> [a] prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

Id.

21. The inquiry presented under the prior "reasonable examiner" standard is whether "a reasonable examiner would have considered such [omitted] prior art important in deciding whether to allow the patent application." Impax Labs., 468 F.3d at 1374 (quoting Digital Control, 437 F.3d at 1314)).

22. The applicable "older three tests" referenced in Digital Control include: (1)

the objective "but-for" standard, in other words, "where the misrepresentation was so material that the patent should not have issued;" (2) the subjective "but-for" test, or "where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so"; and (3) the "but it may have" standard, "where the misrepresentation may have influenced the patent examiner in the course of prosecution." See Impax Labs., 486 F.3d at 1374 n.5 (quoting Digital Control, 437 F.3d at 1315)).

23. After determining that the applicant withheld material information, the court must decide whether the applicant acted with the requisite level of intent to mislead the USPTO. See Baxter Int'l, Inc. v. McGaw Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998). "Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for finding a deceptive intent." Hebert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996). That is, "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Kingsdown, 863 F.2d at 876. A "smoking gun" is not required in order to establish an intent to deceive. See Merck, 873 F.2d at 1422. An inference of intent, nevertheless, is warranted where a patent applicant knew or should have known that the withheld information would be material to the USPTO's consideration of the patent application. See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997).

24. Because a patent is presumed valid under 35 U.S.C. § 282, inequitable conduct requires proof by clear and convincing evidence. See Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 551 (Fed. Cir. 1990). Both the distinct elements of

materiality and an intent to deceive must each be shown by clear and convincing evidence. See Hoffman-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1359 (Fed. Cir. 2003).

25. A determination of inequitable conduct follows a two-step analysis. The withholding of information must first meet threshold findings of materiality and intent. See Molins, 48 F.3d at 1178.

26. If the court finds that these thresholds have been met, the trial court must weigh its findings of materiality and intent to determine whether the balance tips in favor of a conclusion of inequitable conduct. See N.V. Akzo v. E.I. DuPont de Nemours, 810 F.2d 1148, 1153 (Fed. Cir. 1987). The showing of intent can be proportionally less when balanced against high materiality. Id. In contrast, the showing of intent must be proportionally greater when balanced against low materiality. Id.

F. The Boneau Application - Materiality

27. The Boneau application, which issued as Boneau '331 in March 1994, was not disclosed prior to the issuance of the '154 patent in May 1996. The Boneau patent was first disclosed to the USPTO on September 2, 1997 in connection with a later divisional Lau patent application claiming priority to the '154 patent.[7] (DTX-911, IDS at paper 9) Each of the divisional applications that issued as the '133, '167, and '168 patents claimed priority to the '097 application. ACS was not required to disclose Boneau '331 in those patent applications, since Boneau '331 was disclosed in the

[7]The record indicates that Boneau '331 was submitted to the examiner of U.S. Patent Application No. 08/783,033 on September 2, 1997. (DTX-911, IDS at paper 9) Boneau '331 was also submitted to the examiner of the '097 application on September 5, 1997. (DTX-21, IDS at paper 8)

prosecution of the '097 application. The Manual of Patent Examination Procedure ("MPEP") states that an applicant need not resubmit references cited in a parent application because the examiner is required to consider those references when examining a continuing application (such as a divisional application). MPEP § 609.02 (Revision 5, Aug. 2006). "In view of MPEP § 609, it can not be inequitable conduct for an applicant not to resubmit, in the divisional application, the information that was cited or submitted in the parent application." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 537 (Fed. Cir. 1998). Indeed, Boneau '331 appears on the face of each of the '168, '133, and '167 patents. Therefore, for the aforementioned reasons, the '168, '133, and '167 patents are not unenforceable due to inequitable conduct based upon a failure to disclose the Boneau application/Boneau '331.

28. The '790 application was filed on July 28, 1994, and claimed priority to an application filed October 28, 1991. The court, therefore, applies the pre-1992 "reasonable examiner" standard for materiality, noting that the Federal Circuit has specifically stated that this standard was not superceded by Rule 56.[8] See Digital Control, 437 F.3d at 1316 (applying "reasonable examiner" standard in reviewing inequitable conduct during prosecution of a patent filed in 1996 claiming priority to application filed in 1991); see also Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1380 (Fed. Cir. 2001) (applying "reasonable examiner" standard in reviewing omission during prosecution of an application filed in 1993).

[8]For this reason, the court need not analyze what subject matter arose for the first time in the '790 continuation-in-part application and, consequently, would not receive the benefit of the filing date of the parent application. See generally, Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed. Cir. 1984).

29. The court has previously construed the term "cylindrical element" as it appears in the Lau claims to mean "a radially expandable **segment** of a stent having a longitudinal length less than its diameter ["L<D"] with a circumferential undulating pattern."[9] (D.I. 639 at 1883:16-20 (emphasis added))

30. The Boneau application states that

> [t]ypical cardiovascular vessels into which the stent 10 might be implanted range from 1.5 millimeters to five millimeters in diameter, and corresponding **stents** may range from one millimeter to two centimeters [20 mm] in length. However, in most instances the stent will range in length between 3.5 millimeters and 6 millimeters. Preliminary testing of stents having a length between 3.5 millimeters and 4.5 millimeters has been performed with good success outside the United States, and testing on animals is also ongoing.

(Id., col. 5 ll. 25-36 (emphasis added))

31. The selection of a stent diameter at the higher end of the stated range for the diameter of a vessel (e.g. 5 mm) and a length at the lower end of the range stated for stents (e.g. 1 mm) results in a disclosure of a stent with L<D. (D.I. 670 at 167:20-168:20; D.I. 671 at 331:23-333:9) The materiality of this disclosure is not negated by ACS's allegations that a Boneau stent of such a short length would not be functional.[10]

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[9]Under the court's definition, an "undulating pattern" is a "wave-like pattern." (D.I. 615)

[10]There is no evidence of record which conclusively demonstrates whether a Boneau stent with a length shorter than 4 mm would be functional. At trial, ACS suggested that a stent shorter than 4 mm (for example, 1 mm) would not be functional. Medtronic's witnesses testified that the literature available at the time of the Boneau application did not imply that such a short Boneau stent would not work. (D.I. 670 at 170:1-4; D.I. 671 at 335:6-13) Whether the full range of the disclosed "one millimeter to two centimeters in length" range is, in actuality, functional, is not a question that bears on whether the disclosure of the Boneau application is material, only what level of materiality is attached to that information. See Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V., 464 F.3d 1339, 1345 (Fed. Cir. 2006) (As a "general principle," "materiality is not 'negated' simply because the method disclosed in

Nor is it negated by the lack of corroboration for Boneau's claim that he made seven stents less than 4 mm long, the smallest being "[a]bout 2.2 mm," during this timeframe.[11] (D.I. 670 at 107:19-21; 112:3-8) The disclosure, however, is simply a radially expandable **stent** with L<D in one combination. The Boneau application does not disclose "a radially expandable **segment** of a stent" with L<D, or otherwise discuss stents in terms of a combination of discrete segments or elements (which may not function independently as stents).

32. The Boneau application discloses the use of multiple stents to treat a single lesion (Boneau '331, col. 6 ll. 27-28), but does not disclose that multiple stents should be connected together (by sutures or otherwise). There is, therefore, no disclosure of "a plurality of connecting elements" for interconnecting adjacent stent segments as required by the '154 patent claims. Even ignoring the distinction between the "cylindrical elements" of the Lau stents with a stent as a whole, the Boneau application does not specify any configuration for positioning multiple stents on a balloon (or in the vessel) where multiple stents are used to treat a single lesion. There is no disclosure that the stents should be "interconnected so as to be generally aligned on a common longitudinal axis" as required by the '154 patent claims. (Id., col. 6 ll. 36-41 ("In instances where it is known in advance that multiple stents will be the preferred method

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the [prior art] required some modification in order to be operative.").

[11]In support, ACS offered DTX-1319, which consists of two handwritten pages of data tables purportedly written by Boneau and which supposedly memorialize the dimensions of the seven short Boneau stents that he crafted. (D.I. 670 at 117:15-118:15) Boneau conceded that this purportedly corroborative data was undated, unlabeled, and disclosed neither to ACS nor the USPTO as part of the Boneau application. (Id. at 144:14-145:13)

of treatment, a plurality of such stents may be positioned along a single balloon catheter for simultaneous delivery to the affected area.")

33. Materiality "is judged based upon the overall degree of similarity between the omitted reference and the claimed invention in light of the other prior art before the examiner." Baxter Intern., Inc. v. McGaw, Inc., 149 F.3d 1321, 1328 (Fed. Cir. 1998). As discussed supra, the Boneau application does not disclose a stent comprised of elements or segments, but does disclose very short stents which may have L<D and which may be used in multiples to repair a single lesion. Notwithstanding that there is no disclosure of any connectivity regarding multiple stents or their orientation (such as on a common axis), the court is satisfied that a sufficient degree of similarity exists between the Boneau application and the claims of the '154 patent from which to conclude that reference was material.[12]

34. This conclusion is bolstered by the fact that the relevant disclosure of the Boneau application as it pertains to Medtronic's obviousness theory was of short (e.g., 1 mm) stents. At trial, Medtronic's expert, Neil Saigal, Ph.D. ("Saigal"), testified that each of the limitations disclosed in claim 1 of the '154 patent could be found by combining small (e.g., 1 mm) stents disclosed in the Boneau application with the

[12]In view of ACS's concession that it received a copy of the unpublished Boneau application prior to January 1990, and the court's holding that the Boneau application was material, Medtronic's argument that ACS's mid-1990s "Bronco report" (DTX-1014) demonstrates that Lau and/or Orth had knowledge of the Boneau stent which could have only been obtained from the Boneau application is moot. (D.I. 683 at 18; D.I. 687 at 7) Further, the testimony presented at trial indicated that the Bronco report did not accurately describe the Boneau stent. (See, e.g., D.I. 671 at 468:12-469:8) The court declines to weigh the contents of the Bronco report in its evaluation of the materiality of the Boneau application vis-a-vis the '154 patent.

disclosure of connecting members in United States Patent No. 5,102,417 to Palmaz ("Palmaz '417") or United States Patent No. 5,195,984 to Schatz ("Schatz '984"). (D.I. 636 at 1367:1-1369:19, 1372:5-13; D.I. 671 at 340:8-22) Specifically, Saigal testified that the literature indicated that stents described by Palmaz '417 were 7 mm long and connected by a bridge.[13] (D.I. 636 at 1367:11-18) Saigal also testified that Schatz '984 provides small connecting elements. (Id. at 1372:14-19) With respect to motivation to combine, Saigal cited to the testimony of inventor Schatz that he was looking for "the shortest [stent] segment as possible" so that greater flexibility and deliverability could be achieved. (Id. at 1370:10-25, 1371:17-22, 1374:8-12)

35. The inquiry is not whether the Boneau application would have actually formed the basis for an obviousness rejection during prosecution, rather, whether the examiner would have considered it important in deciding whether to reject one or more claims. See American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1362 (Fed. Cir.1984); see also Digital Control, 437 F.3d at 1318 ("Under the 'reasonable examiner' standard, a misstatement or omission may be material even if disclosure of that misstatement or omission would not have rendered the invention unpatentable.") (collecting cases). Based upon the foregoing, the court is persuaded that sufficient similarities exist between the disclosure of the Boneau application and the '154 patent claims to conclude that a reasonable examiner would have wanted to evaluate the Boneau application, whether or not he would have ultimately elected to form an obviousness rejection drawing from any of the disclosures of the Boneau application

[13]Saigal referred to the Handbook of Coronary Stents in this regard. (DX-103; DX-104; D.I. 636 at 1280:4-25)

(such as stent length), or not.[14]

G. The Boneau Application - Cumulativeness

36. In ACS's view, the Boneau application is cumulative to U.S. Patent No. 5,123,917 to Lee ("Lee '917"),[15] which was submitted at the beginning of the prosecution of the Lau patents, because it "discloses every feature of Boneau that Medtronic touts as being relevant to the Lau claims." (D.I. 686 at 32) Lee '917 generally discloses a stent with an inner layer (10), to which a plurality of separate and expandable ring-like scaffold members (30) are connected, and an outer layer (20) which encloses the inner tube. (Lee '917, col. 2 ll. 34-53, figs. 1, 2, 4, 5) ACS asserts that both the Boneau application (fig. 6a) and Lee '917 (fig. 5) "disclose stainless steel, balloon-expandable, zigzag structures for use in coronary arteries." (D.I. 686 at 32) The zigzag structure disclosed in the Boneau application is the stent itself. (Boneau '331, col. 6 ll. 42-49) There is no evidence of record, however, that the ring-like scaffold members disclosed in Lee '917 are, in and of themselves, functional stents.[16] (Lee

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[14]ACS's assertion that the USPTO never actually issued any rejections based on Boneau during the prosecution of the Lau patents is not persuasive. (D.I. 686 at 29) Further, ACS's assertion that the jury verdict of validity in this case is also evidence of non-materiality is equally unpersuasive, and inconsistent with the "reasonable examiner" standard. (Id. at 30) The court notes that the examiner's rejection of the '154 patent during reexamination over Boneau '331 is consistent with the court's finding of materiality. (D.I. 708, Ex. 1 at 11-12)

[15]Medtronic's assertion that Lee '917 is somehow "not even prior art to the Lau patents because Mr. Lau could have sworn behind the Lee filing date" is without merit. (D.I. 687 at 9)

[16]ACS's arguments that "[f]igs. 1 and 2 of Lee ['917] clearly show that **each ring** has L<D in both the delivery and expanded state" and also "depict multiple **rings** being delivered on a single balloon" likewise ignore this distinction. (D.I. 686 at 32 (emphases added))

'917, col. 5 ll. 16-17 & 25-43, fig. 4) Of course, as noted above, there is no evidence of record that short segments (e.g., <4 mm) of any kind function as stents. On this record, the court is not persuaded that the examiner would have found Lee '917 more significant to the issue of the patentability of the Lau claims than Boneau '331. The court, therefore, declines to hold that Boneau '133 was cumulative to Lee '917.

37. The '790 application was rejected during prosecution as anticipated pursuant to 35 U.S.C. § 102(e) by Palmaz '417. The examiner rejected original claims 1-4 and 8-22, stating that Palmaz '417 teaches a stent comprising "a plurality of cylindrical elements 72; a plurality of parallel connecting elements 100, see fig. 7; . . . [and] in an expanded condition, each cylindrical element has a length less than its diameter, as seen in fig. 10[.]" (AX-11 at 46) In response, ACS stated that:

> [W]hen the [e]xaminer rejects claims 1-4 and 8-22 by saying that the '417 patent teaches "a plurality of parallel connecting elements 100, see Fig. 7," the [e]xaminer is actually referring to a plurality of prostheses or grafts being connected together by connecting elements. As clearly pointed out, [a]pplicants have not connected a plurality of stents together by connecting cylindrical elements. Applicants have formed one stent by connecting a plurality of cylindrical elements together. The cylindrical elements, in and of themselves, are not stents which function for the stated purpose. The Palmaz '417 patent connects a plurality of grafts with connecting elements 100, but it does not teach connecting cylindrical elements together to form one graft.

(Id. at 124) ACS emphasized that "[e]ach of the expandable cylindrical elements 11 of [a]pplicants['] invention cannot be construed to be an individual stent or graft. . . . a single cylindrical element 11 would be incapable of functioning as a stent" because it "could not possibly hold open and support the vessel wall after it was expanded." (Id. at 123-24) The claims were thereafter allowed. (Id. at 127)

38. As noted by the examiner, Palmaz '417 discloses a stent with L<D in the

expanded state (as seen in figure 10). (AX-11 at 46) Saigal testified that when certain of Boneau's disclosed measurements are compared, the Boneau application discloses a stent with L<D in the expanded state, the crimped state, and in the "as manufactured" state. (D.I. 683 at 26; D.I. 671 at 329:20-333:23) As relevant to the '154 patent, however, neither reference discloses "a radially expandable segment of a stent" with L<D as required by the '154 claims, only L<D for the stent itself. Therefore, there is no true distinction between the disclosures of the Boneau application and Palmaz '417 regarding L<D. Unlike the Boneau application, which did not describe any connection between multiple stents when used in one vessel, Palmaz '417 discloses a plurality of prostheses or grafts connected together by connecting elements. (AX-11 at 46) Palmaz '417, thus, is closer prior art to the '154 claims than the Boneau application. Medtronic admitted as much when it argued at trial that Palmaz '417 was an anticipatory reference to the '154 patent (D.I. 627), while the Boneau application was asserted only as an obviousness reference. Accordingly, the Boneau application was cumulative of Palmaz '417, and cannot form the basis for rendering the '154 patent unenforceable due to inequitable conduct. See Digital Control, 437 F.3d at 1319 ("[A] withheld otherwise material prior art reference is not material for the purposes of inequitable conduct if it is merely cumulative to that information considered by the examiner.").[17] Because the court finds that the Boneau application was cumulative to Palmaz '417, which was before the examiner, the court shall not address the facts

[17]At trial, ACS asserted that the Boneau application was also cumulative to U.S. Patent No. 4,580,568 to Gianturco, which disclosed a self-expanding stent. (See, e.g., D.I. 670 at 25:23-24:3) ACS has apparently abandoned this position, as it has not asserted its argument in its post-trial briefing. (D.I. 686)

surrounding ACS's purported intent to deceive.

H. The Balance of the "Boneau Prior Art"

39. According to Medtronic, ACS withheld from the USPTO during the prosecution of all four Lay patents "clinical data showing implantation of Boneau rings in a crown to crown configuration, and the connection of such rings at their crowns" with sutures.[18] (D.I. 683 at 5-6, 24, 27-28) The "clinical data" referred to by Medtronic consists of information purportedly shared by Boneau and Stertzer during their discussions and meetings with ACS, most notably their August/September 1990 presentation.[19] Collectively, Medtronic characterizes this information as "the Boneau prior art," though the precise scope of this term is unclear. According to Medtronic, ACS was: (1) shown angiograms of stents showing a crown to crown configuration; (2) informed by Stertzer that he had implanted multiple stents in a crown to crown fashion; (3) informed of Boneau's idea to connect his stents together with sutures; and (4) shown several prototype Boneau stents. The court will analyze the materiality of these

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[18]As discussed supra, this information was not disclosed in the Boneau patent application.

[19]Prior to the August/September 1990 meeting, there is no evidence of record that ACS was given any information which was not contained in the Boneau patent application. Boneau testified that when he met with Sampson in May 1989, he showed him some prototypes. (D.I. 670 at 113:19-114:10; 142:17-21) This testimony was in contradiction to Boneau's prior deposition testimony, used as impeachment evidence, whereby Boneau had stated that he "did not show or give prototypes to ACS in May of 1989." (Id. at 156:6-157:11) Boneau stated, however, that he did not disclose anything at that time that was not in his patent application. (Id. at 142:1-3) Although Boneau and Stertzer testified that they met with ACS on a number of other occasions before the August/September 1990 presentation (id. at 61:14-20; 104:1-7), Medtronic has not put forward evidence that any additional information was given to ACS during any such encounters.

purported disclosures in turn.

1. Crown to crown orientation

40. The '133, '167, and '168 patents have claims requiring that the cylindrical elements of the stent are aligned in a crown to crown or out of phase orientation.[20] The Boneau patent application does not disclose a crown to crown placement of multiple Boneau stents. (D.I. 670 at 144:1-3; 181:11-15)

41. Stertzer testified that he always tried to implant multiple Boneau stents in a crown to crown orientation to "the best of his ability" (id. at 67:11-16; 71:8-11), and in fact, implanted four stents in a man in 1989 in this fashion (id. at 46:13-25; 100:18-25). Boneau did not recall telling ACS about crown to crown placement in 1989 (id. at 144:1-6), but both Boneau and Stertzer testified that no information that they had about the Boneau stent was withheld from ACS during their August/September 1990 presentation.[21] Stertzer testified that this included his crown to crown placement of Boneau stents. (Id. at 100:18-101:4) Both Lau and Orth testified to the contrary. (D.I.

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[20]All claims of the Lau '167 patent contain this requirement. Claims 5-8 and 12-18 of the '168 patent, and claim 11 of the '133 patent, also require a crown-to-crown or out of phase orientation.

[21]Specifically, Stertzer testified that he shared "clinical data, any pre-clinical and pathologic data that [they] had, and some angiography showing demonstrations of how it was appearing after they were implanted in human beings." (D.I. 670 at 66:24-67:2) Boneau stated that he

> had three meetings with them and [he] had probably a total of about four and a half, five hours total of those three meetings, and when those meetings were over, they knew as much about, and probably more because – about making the Boneau stent and using the Boneau stent than [he] did.

(Id. at 126:22-127:2)

671 at 481:17-21; D.I. 670 at 400:12-25)

42. As corroborating evidence, Medtronic points to several angiograms shared with ACS at the 1990 presentation which purportedly show "multiple Boneau stents both mounted on a balloon in a crown-to-crown configuration or 'out of phase' configuration and implanted in an artery."[22] (D.I. 683 at 13) Several of these angiograms were introduced during trial. (DTX-227; DTX-495; DTX-497)

43. With respect to DTX-497, Boneau admitted that this angiogram did not clearly show a crown to crown or out of phase configuration. (D.I. 670 at 159:2-7 ("I don't think anyone can [tell].")) Stertzer testified that DTX-495 depicts several stents in a crown to crown orientation. (D.I. 670 at 45:4-6) The testimony of Stertzer and Boneau conflict as to whether ACS was actually shown DTX-495 which, coincidentally, is undated. (Compare id. at 85:2-24 with 131:12-18; id. at 85:2-24) No ACS witness confirmed seeing this angiogram in 1990. The court is not persuaded that ACS had sufficient information regarding DTX-495 to have required its disclosure to the USPTO. See Life Technologies, Inc. v. Clontech Laboratories, Inc., 224 F.3d 1320, 1327 (Fed. Cir. 2000) (inventors who were "in possession of only very limited information" regarding competitor's work, and who could have, "[a]t most . . . disclosed to the PTO that a rival researcher claimed to have reduced RNase H activity in cloned RT and had presented his results at a conference, which neither of the inventors attended," did not commit inequitable conduct by their non-disclosure, as the information "lack[ed] the specificity

[22]Boneau testified that he "took some pictures, some drawings, and other paraphernalia" with him to the 1990 presentation, and showed ACS "pictures of multiple stents on a balloon." (D.I. 670 at 126:6-7; 126:15-16)

and definiteness required to support a patentability rejection under 35 U.S.C. § 102(g)."); see also FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987) (stating that an applicant "must be chargeable with knowledge of the existence of the prior art or information, for it is impossible to disclose the unknown."). Even assuming that this angiogram was shown to ACS, however, DTX-495 is no more informative than DTX-497 and, therefore, could not clearly convey to ACS a series of Boneau stents in a crown to crown orientation. For all of these reasons, the court declines to find that DTX-497 or DTX-495 are material prior art to the '167, '168, and '133 patents.

44. As with the other angiograms, DTX-227 is undated. Boneau testified that DTX-227 was shown to ACS, but no ACS witness corroborated seeing this specific angiogram. (Id. at 127:3-12, 128:7-8) Boneau also testified that DTX-227 depicts three stents in a "semi-crimped" state: the first two are crown-to-crown, and the latter two are in phase. (Id. at 128:7-21; 129:5-22) According to ACS, this angiogram "actually proves that crown to crown placement was not important at all," since three stents are depicted as mounted as both out of phase and in phase on the same balloon. (D.I. 686 at 18) ACS's expert, Dr. Segal, testified that it was well known in the art to connect stents in an out of phase configuration by 1990. (D.I. 671 at 590:20-591:4)

45. As an initial matter, it is not clear that ACS had sufficient knowledge of DTX-227 so as to invoke the duty of disclosure. See Life Technologies, Inc., 224 F.3d at 1327; FMC Corp., 835 F.2d at 1415. Additionally, the Lau patent claims require successive cylindrical elements oriented out of phase to adjacent cylindrical elements,[23]

[23]Claims 1 and 5 of the '167 patent state that "the undulating pattern of **each** of the cylindrically shaped elements [is] out of phase with the undulating pattern of **each** of

while DTX-227 depicts one pair of stents in phase and another pair out of phase. DTX-227 provides no indication that the out of phase arrangement of the two stents was important, or even intentional. The court finds that Medtronic has not presented clear and convincing evidence that a reasonable examiner would have been substantially likely to consider DTX-227 important in deciding whether to allow the '133, '167, or '168 patents.

46. Stertzer testified that he informed ACS of his implantation of four stents in a man in 1989 in the crown to crown orientation. (D.I. 670 at 46:13-25; 100:18-25) His testimony is generally supported by Boneau's testimony, and controverted by that of Lau and Orth. Aside from the angiograms discussed supra, however, there is no documentary or other evidence to support Stertzer's testimony that he implanted stents in a crown to crown fashion. Although the Federal Circuit has not specifically addressed whether uncorroborated testimony can suffice to meet a defendant's burden of proving inequitable conduct, the court declines to hold that an uncorroborated prior use can be used to render an entire patent unenforceable. Compare Dow Chem. Co. v. Mee Indus., Inc., 341 F.3d 1370, 1371 (Fed. Cir. 2003) ("Corroboration is required of any witness whose testimony alone is asserted to invalidate a patent, regardless of his or her level of interest.") (quoting Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d

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the adjacent cylindrically shaped elements." (Emphasis added) Claim 11 of the '133 patent states that "the shapes of adjacent cylindrical elements are out of phase" and, similarly, claim 12 of the '168 patent states that the cylindrical elements are aligned "so that the peaks are out of phase." The use of the term "the" in these contexts strongly implies that all of the cylindrical elements must be out of phase. See gen. Free Motion Fitness, Inc. v. Cybex Intern., Inc., 423 F.3d 1343, 1350-51 (Fed. Cir. 2005) ("Like the words 'a' and 'an,' the word 'the' is afforded the same presumptive meaning of 'one or more' when used with the transitional phrase 'comprising.'").

1193, 1217 (Fed. Cir. 2002) (quoting Finnigan Corp. v. Int'l Trade Comm'n, 180 F.3d 1354, 1369 (Fed. Cir. 1999), cert. denied, 538 U.S. 1058 (2003))); Price v. Symsek, 988 F.2d 1187, 1194 (Fed. Cir. 1993) ("[A]n inventor's testimony respecting the facts surrounding a claim of derivation or priority of invention cannot, standing alone, rise to the level of clear and convincing proof"). In addition, there is no evidence of record that tends to shed light on the exact nature and scope of this purported disclosure. Thus, there is no indication that ACS had sufficient knowledge of Stertzer's practice so as to invoke the duty of disclosure. See Life Technologies, Inc., 224 F.3d at 1327. For the aforementioned reasons, the court declines to find that Medtronic has demonstrated by clear and convincing evidence that Stertzer's "practice" regarding his crown to crown placement of Boneau stents was material prior art to the '133, '167, or '168 patents.

2. Boneau's idea to connect Boneau stents with sutures

47. The '133 and '167 patent claims require that the cylindrical elements are interconnected, the '154 patent claims require the presence of particular "connecting elements," and the '168 patent claims specify that the cylindrical elements are connected with weld connections.

48. Boneau testified that he told ACS about connecting multiple stents with sutures and, to do this, the stents would have to be oriented crown to crown. (D.I. 670 at 137:13-138:2) Although Boneau testified that he came up with the sutures idea in March 1990, he admits he has "no other evidence" to corroborate his story. (Id. at 152:3-20; 153:9-11) No other witness testified that ACS was told about Boneau's

idea.[24] The Boneau patent application does not disclose connecting Boneau stents with sutures. (Id. at 153:2-5) Boneau claims that he connected some stents together in bench testing (id. at 138:5-9), however, none of the prototypes shown or given to ACS were connected (D.I. 671 at 400:12-25). Thus, there is no indication that ACS had sufficient knowledge of Boneau's idea or practice so as to invoke a duty of disclosure. See Life Technologies, Inc., 224 F.3d at 1327. Further, as discussed supra, the court declines to hold that Boneau's uncorroborated testimony regarding his bench testing of suture connections can suffice to meet defendant's burden of proving inequitable conduct. On this record, the court declines to find that Medtronic has demonstrated by clear and convincing evidence that Boneau's "suture stent" was material prior art.

3. Prototypes

49. ACS was given "between a few and a dozen" prototypes at the 1990 presentation. (D.I. 671 at 398:16-20) Lau testified that the prototypes were pre-mounted on balloons, with only one stent per balloon. (Id. at 481:7-16) There is no indication in the record that these stents were any different from those disclosed in the Boneau patent application.

50. Specifically with respect to the '154 patent, there is no evidence that the prototypes given ACS at the 1990 presentation had L<D. The vast majority of evidence

[24]Stertzer testified that he told ACS he liked the Boneau stents because he could put multiple devices on a balloon to cover the majority of a lesion, or just use one for a short lesion. (D.I. 671 at 308:11-16) Stertzer did not discuss the use of sutures. Similarly, Orth testified that he recalled from the August/September 1990 meeting that "you could tailor the length of the device – devices you were delivering by putting multiple units on a balloon." (Id. at 399:7-9) Again, Orth did not mention any discussion of the use of sutures. The evidence of record tends to contradict Boneau's testimony that he told ACS about connecting Boneau stents with sutures.

suggests that the stents showed or given to ACS were "all about 4 to 7 millimeters." (D.I. 671 at 398:16-20) For example, Lau had a "very specific recollection that [Boneau and Stertzer] disclosed that [the stents] could be either 4 or 7 millimeters long." (Id. at 479:4-9) Stertzer himself, a witness for Medtronic, did not specifically recall working with stents shorter than 4 millimeters prior to 1992. (D.I. 670 at 94:14-95:4) Exhibit DTX-482, "a picture of a . . . prototype of a stent that [Boneau] had given to Mr. Orth," signed by Orth on September 21, 1990, was introduced at trial. (Id. at 131:19-132:12) Boneau testified that he could not identify the length of the stent depicted in DTX-482.[25] (Id. at 157:21-158:10) However, it appears from the scale of the picture that the stent length exceeds 4 mm. (DTX-482)

51. Because there is no indication that the prototypes shared with ACS at the August/September 1990 meeting were different from the stents disclosed in the Boneau application, the court's analysis with respect to the Boneau application applies with equal force. That is, the prototypes meet the threshold of materiality under the "reasonable examiner" standard. The teachings which would result from the examination and/or testing of these prototypes, however, would also be cumulative to Palmaz '417 which was before the examiner during the prosecution of each of the Lau patents.

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[25]The court notes that DTX-482 is much clearer than the angiograms introduced as DTX-495 and DTX-497, and includes a 2.00 mm measurement scale. It is ironic that Boneau, a person of skill in the art of stents, could not clearly identify the length of this stent even given this scale, yet this court is asked to find that DTX-495 and DTX-497, alone or in combination with other references, were material references which could serve to render the Lau patents unenforceable.

III. CONCLUSION

For the reasons discussed above, the court concludes that Medtronic has failed to prove, by clear and convincing evidence, that the '133, '154, '167, and '168 Lau patents are unenforceable due to inequitable conduct in the prosecution of the patents based on the Boneau application or "the Boneau prior art." Judgment shall be entered in favor of ACS. An appropriate order shall issue.